

REMARKS

The Office Action of October 14, 2009, has been carefully studied. The claims in the application are now claims 19 and 27 only, and these claims define novel and unobvious subject matter and meet all the requirements of §112, whereby allowance is fully warranted. Applicants again request favorable reconsideration and allowance.

Main claim 19 is substantially amended above and claims 23-26 are cancelled without prejudice in favor of more compact prosecution at the present time, but Applicants explicitly reserve the right to return at a later time to any subject matter deleted by the above amendments, Applicants relying on the provisions of 35 USC §120.

Claims 19 and 23-26 have been rejected under the first paragraph of §112 as failing to comply with the written description requirement on the basis of the recitation in claim 19 that the active ingredients in the unit dosage form composition administered are "only" at least one phytoestrogen and the carotenoid(s). The rejection is respectfully but strenuously traversed.

As will be pointed out below in substantial detail, Applicants' specification is very clear to anyone reading such specification, of course including those skilled in the art, that the composition administered may indeed comprise **only** the phytoestrogen and the carotenoid. But before enumerating how and where this is made clear in Applicants' specification, Applicants would like to start with the law.

In this regard, attention is first respectfully invited to the very recent decision in *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010), a precedential decision of an expanded Board including Director Kapos, Deputy Director Barner, Chief Administrative Patent Judge Fleming, Vice Chief Administrative Patent Judge MacDonald and three additional administrative patent judges:

The Examiner has the initial burden to set forth the basis for any rejection so as to put the patent applicant on notice of the reasons why the Applicant is not entitled to a patent on the claim scope that he seeks....

In the present case, the Examiner's main point appears to be that he cannot find the word "only" and therefore "this limitation introduces new matter into the claims." That, however, ignores the crucial issue of whether or not the subject matter in question is implicit. In other words, what the examiner has not considered is the issue of *Ipsis Verbis* or "in haec verba".

It is well accepted in the Patent Law that a statement may be added to a specification or claim even though there is no explicit support in the original specification, and the added material will not be considered to be "new matter" so long as there is implicit support in the original specification. The Supreme Court of the United States so held in *Marconi Wireless Telegraph Company of America v. United States*, 320 US 1, 57 USPQ 471. Also see *In re Wright*, 145 USPQ 182, and *Reeves Instrument Corporation et al v. Beckman Instruments Incorporated*, 161 USPQ 450, 476 (Finding I2), 481 (Conclusion 25). It has been stated that the applicant's "disclosure includes not only whatever is explicitly shown and described in the application, but also what

is fairly to be inferred from the application taken as a whole," citing *Wezel & Naumann Aktiengesellschaft v. Alexander Leunis, Inc., et al*, and *Morgan Lithograph Co.* 6 USPQ 154, Cert. denied 285 US 545. Also see *Ace Highway Products Corporation v. The D.S. Brown Company et al*, 167 USPQ 129.

In the *Marconi Wireless* case, *supra*, Mr. Chief Justice Stone, speaking for the Court, stated the following (57 USPQ at 483 (Decided June 21, 1943)):

Stone's patent, ... makes explicit, as the patent law permits, what was implicit in Stone's application. By amendments to his specifications made April 8, 1902, he recommended that the frequency impressed upon the vertical conductor at the transmitter "may or may not be the same as the natural period or fundamental of such conductor" and that the antenna circuit at the transmitter "may with advantage be so constructed as to be highly resonant to a particular frequency and the harmonic vibrations impressed thereon may well be of that frequency". Since Stone used as variable inductance to alter at will the frequency of the charging circuit, this direction plainly indicated that the frequency of the antenna circuit might also be variable, and suggested the inclusion of the well-known Lodge variable inductance in the construction of the antenna circuit to achieve that result. ...

... The amendments thus merely clarified and explained in fuller detail two alternative means which could be employed in the invention described in the original application, one of those means being the construction of the antenna so as to be highly resonant, i.e., tuned, to a particular frequency.

In *Acme Highway Products Corp. v. The D.S. Brown Co.*, et al, *supra* (167 USPQ at 133) it was stated:

The law is clear that subject matter may be added to an application by way of amendment ..., without impairment to the right of the original filing date, where the added subject matter is "something that might fairly be deduced from the original application".  
[citations omitted; emphasis added]

In *The Reeves Instrument Corp. et al v. Beckman Instruments, Inc.* case, *supra*, the Court stated:

12. The specification and drawings for the patent in suit were filed as part of the original application... Between the time of original filing and the grant of the patent, no new matter was added to the original disclosures. Although there were a few minor editorial revisions thereof, the specification remained essentially unchanged. The minor changes to the drawings, made at the direction and with the consent of the Patent Office Examiner, merely illustrated conventional ground connections already implicit in the original specification. (emphasis added)

25. The subject matter of claims 7, 8 and 13 of the patent in suit are directed to the same invention originally disclosed, set forth in the objects of the invention, and claimed in the application for the patent in suit as filed, and go no further than to make express what would have been regarded as the equivalent of the specific subject matter originally claimed. No new matter was added to the drawings or specification at any time after the patent application was filed.... (emphasis added)

The question of "new matter" in the addition of implicit material to an originally filled specification was discussed at length by the CCPA its decision *In re Wright* (1965), *supra*, 145 USPQ at 186-188. After reviewing the specification, which the appellant argued implicitly supported the terms added to the claims (which the Patent Office held to be "new matter"), the Court concluded that, in fact, the terms subsequently added were implicitly supported by the original specification. Here is what the Court stated (page 188):

..., we have studied the four passages, indicated in the solicitor's brief as having been stipulated as not part of the original specification, but which nevertheless appear in the record, and conclude that these passages do not add "new matter" to the specification. ...

We feel that the amendments to the specification merely render explicit what had been implicitly disclosed originally, and, while new language has certainly been added, we are not prone to view

all new "language" *ipso facto* as "new matter". (emphasis in original)

Attention is also respectfully invited to *In re Anderson*, 176 USPQ 331, 336. In this case, original claim 2 was amended to delete "containing" and insert therefor --carrying--, the term "carrying" never appearing in the original disclosure. Here is what the Court stated:

It is true that the term 'carrying' does not appear in the specification in this connection. Neither does the term 'containing,' except as it appeared in original claim 2. ...

The question, as we view it, is not whether 'carrying' was a word used in the specification as filed but whether there is support in the specification for employment of the term in a claim; is the concept of carrying present in the original disclosure? We think it is. We think disclosure of the primary layer as a 'vehicle' for the medication is quite sufficient for this purpose. ...

We will not sustain this rejection. (emphasis in original)

Moreover, the burden initially is on the Examiner. Thus, it has been stated, noting *In re Edwards et al*, 196 USPQ 465, 469:

The burden of showing that the [subject matter in question] is not described in the application rest on the Patent and Trademark Office in the first instance, and it is up to the Patent and Trademark Office to give reasons why a description not in *Ipsis Verbis* is insufficient. In re Salem, ... 193 USPQ 513, 518...; In re Wertheim, ... 191 USPQ at 98. [emphasis in original]

It is accordingly beyond question that terminology may properly be added to a specification and/or claims, if the subject matter is implicitly supported in the original disclosure without the added language being considered prohibited "new matter".

The law in these regards has not changed. Please see, for example, MPEP 2163:

While there is no *in haec verba* requirement, newly added claim limitations must be supported by the specification through express, implicit, or inherent disclosure.

And:

The examiner has the initial burden... of presenting evidence or reasons why a person skilled in the art would not recognize that the written description... produces support for the claims. There is a strong presumption that an adequate written description of the claim invention is present in the specification as filed,... [citation omitted]

And:

An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. [citations omitted]

And MPEP 2163.02

The subject matter of the claim need not be described literally (i.e., using the same terms (or *in haec verba*) in order for the disclosure to satisfy the description requirement.

It is therefore clear that the mere fact that the exact expression in claim 19 does not appear in the specification is insufficient basis to maintain that the language is "new matter" or subject matter which falls outside the written description requirement.

Applicants strongly but respectfully maintain that the claim language is implicitly supported throughout Applicants' specification, including at the following locations:

1. Page 10, lines 6-8: "The compositions comprise a physiologically effective amount of at least one hormone and at

least one carotenoid in an amount effective to prevent such adverse effects." No other material is mentioned.

2. Page 10, lines 11-13: "It has surprisingly been found that various combinations of lycopene, phytoene and phytofluene demonstrate a beneficially synergistic effect in preventing the adverse effects associated with the administration of hormones." No other material is mentioned.

3. Page 12, lines 3-7: "Co-administering at least one carotenoid to a phytoestrogen-consuming subject... attenuates the risk for cancer which is associated with the consumption of phytoestrogens. The present invention encompasses a unit dosage form suitable for once daily administration to a human comprising a physiologically effective amount of at least one phytoestrogen and at least one carotenoid,..." Again, only the two components are mentioned as constituting the "present invention."

4. Page 12, last sentence, and pg. 13, first sentence: "A further embodiment of the instant invention is a unit dosage form suitable for once daily administration to a human comprising a physiologically effective amount of at least one hormone, ... and at least one carotenoid... This unit dosage form can prevent the adverse effects associated with the administration of such hormones without inhibiting the beneficial activity of such hormones." Thus, this "further embodiment of the instant invention" includes only the two active components, namely the hormone and the carotenoid.

5. Page 14, lines 4-6: "Accordingly, a composition of the instant invention comprising at least one phytoestrogen and

at least one carotenoid, can be administered to a subject... in order to prevent the additive adverse affects...." Again, it is only these two active materials which are mentioned and which are significant, and therefore these are the **only** components necessary.

6. The examples pages 16-20 and the drawings: In all the examples, the only active components were the phytoestrogens (e.g. isoflavones), and the carotenoids.

Applicants' specification makes it very clear that the Applicants had possession of an invention in which the only active components are the carotenoid and the phytoestrogen, and this is absolutely adequate under the law.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 19 and 23 have been rejected under §103 as obvious from Jackson. This rejection is again respectfully traversed for the reasons of record, respectfully repeated by reference.

Nevertheless, Applicants need not address this rejection at the present time in view of the fact that claim 19 has been amended to incorporate the dependent parts alternatively from claims 24-26, and claims 24-26 have not been rejected as obvious from Jackson. Applicants understand that this rejection is not intended by the PTO to apply to claim 19 in its present form.



Claims 19 and 24-26 have been again rejected as obvious under §103 from Jackson in view of Schlipalius. This rejection is respectfully traversed for the reasons of record, respectfully repeated by reference, and for the following additional reasons as well.

Jackson describes dietary supplements designed to meet a woman's health needs at different life stages. One of the various active ingredients described by Jackson is phytoestrogen, supplemented in order to reduce the risk for developing cancer (col.9 lines 55-59, col.1 lines 42-44). However, as explained in the present application, phytoestrogens exert their anti-proliferative effects only at very high, super-physiological blood concentrations. At physiological concentrations, phytoestrogens are found to increase the risk for the development of hormone-dependent cancers.

Jackson teaches administration of phytoestrogen in order to reduce the risk for developing cancer caused by other agents present in the body of the subject being treated. This is the complete opposite of the present invention, in which phytoestrogens are administered as HRT agents which are actually expected to increase the risk for developing cancer. The method of the present invention comprises the administration of carotenoids in order to prevent or reduce the proliferative effect caused by the simultaneous administration of phytoestrogen.

Schlipalius teaches a carotenoid-containing composition. The entire publication is concerned with the technical steps involved in producing such a composition and provides no teaching whatsoever either for the anti-

proliferative effect of the carotenoids or for specific synergistic carotenoid combinations. The present invention describes a synergistic effect of a combination of lycopene, phytoene and/or phytofluene.

Figure 6 of the instant application clearly demonstrates the greatly enhanced anti-proliferative activity of a mixture of lycopene and phytoene in physiological concentrations in comparison with their activity when administered separately. The synergistic effect of the components could not be predicted or expected based on the knowledge provided by prior art. Schlipalius provides absolutely no hint or suggestion which would have motivated the skilled artisan to attempt to use a combination of lycopene, phytoene and/or phytofluene to obtain a synergistic anti-proliferative effect.

The law is clear as confirmed in *Ex parte Frye, supra*, that the burden is on the PTO to provide reasoning sufficient to reach the legal conclusion of obviousness. In this regard, rejections on the basis of alleged obviousness cannot be sustained by mere conclusory statements, but instead the PTO must provide a valid rationale for any proposed combination. Applicants in this regard respectfully challenge the sufficiency or basis of the rationale for combining the references as set forth in the rejection. The mere fact that Schlipalius discloses carotinoids and indeed incidentally mentions that mixtures of carotinoids can be used, does not make it obvious to use mixtures in the composition of Jackson.

Even more so, the disclosure of Schlipalius does not make it obvious to select from the listing of carotinoids

disclosed, the mixture of lycopene together with phytoene and/or phytofluene.

Moreover, and importantly, the proposed combination, even if it were obvious (respectfully, not admitted), would not result in the exclusion of components which are required by Jackson.

Furthermore, Applicants respectfully reiterate the fact that there is nothing in the prior which would have led the person of ordinary skill in the art to reasonably expect the synergistic effects achieved according to the present invention.

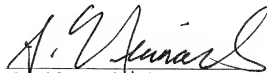
Withdrawal of the rejection is in order and is respectfully requested.

If the Examiner has any questions or suggestions, he is respectfully requested to contact the undersigned at (202) 628-5197.

Respectfully submitted,

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